

Section II (Remarks)

Amendment to the Claims

Claims 49 and 58 have been amended to recite the limitation “wherein urea and water in combination constitute greater than 50% by weight of the composition.” Such recital is consistent with and supported by the disclosure of the application, e.g, paragraph [0027], which describes urea as being present in the amount of 1-50%.

At the upper limit of urea concentration (50%), the additional presence of water in the formulation means that urea and water will necessarily constitute greater than 50% in the formulation. See also Tables 4 and 5 of the application, according to which the amount of urea and water is 79.1% and 76.7%, respectively.

Accordingly, no new matter within the meaning of 35 U.S.C. §132(a) has been introduced by the amendment of claims 49 and 58.

Rejection of Claims 49-62 under 35 USC § 112 First Paragraph

The May 1, 2008 Office Action rejected claims 49-62 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, on the basis that the claims recite limitations that cannot be found explicitly or implicitly in the original disclosure as filed, and therefore constitute new matter.

Applicant disagrees and traverses the rejection, for the following reasons.

Law regarding the Written Description requirement

It is well settled law that “to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (M.P.E.P. section 2162.02)

Section 2163.06 of the M.P.E.P further describes the relationship of the written description requirement to new matter as follows:

Lack of written description is an issue that generally arises with respect to the subject matter of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. Stated another way, information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter. (emphasis added) MPEP 2163.06

Disclosure in the Specification and Claims of the Application

Table 1, at paragraph [0027] of the application beginning at page 6, line 22, and continuing to paragraph [0029], at page 8, line 4, set out in pertinent part below, specifies concentration ranges by weight for ingredients of applicants' dermatologic composition, including urea, shea butter, soybean sterol, and sunflower oil.

TABLE 1

Component	Concentration Range, Weight %	Alternative Components
Urea	1%–50%	ammonium lactate; glycerin; various combinations of these main and alternative components
<i>Butyrospermum</i> <i>Parkii</i> (Shea Butter) Fruit	0.5%–10%	cocoa butter, vegetable jojoba esters, cera alba (Beeswax), jojoba oil (<i>Simmondsia</i> <i>Chinensis</i>), castor oil, PEG 1500, PEG 400, and modified vegetable oil "butters," mango butters

<i>Glycine Soja</i> (Soybean) Sterol	1.0%–4.0%	plant-derived steroid alcohols (e.g., sitosterol, stigmasterol, campesterol, brassicasterol, lanosterol, 7-dehydrocholesterol) and/or lecithin
<i>Helianthus Annuus</i> (Hybrid Sunflower) Oil	2.0%–15%	oxidation-stable natural oils, e.g., oil obtained from plants such as rapeseed (<i>Brassica</i> spp.), soybean (<i>Glycine max</i>), oil palm (<i>Elaeis guineensis</i>), coconut (<i>Cocos</i> <i>nucifera</i>), castor (<i>Ricinus</i> <i>communis</i>), safflower (<i>Carthamus tinctorius</i>), mustard (<i>Brassica</i> spp. and <i>Sinapis alba</i>), coriander (<i>Coriandrum sativum</i>) linseed/flax (<i>Linum</i> <i>usitatissimum</i>), thale cress (<i>Arabidopsis thaliana</i>) and maize (<i>Zea mays</i>)

As is apparent from the disclosure of Table 1, a composition with ingredients limited to the ranges of 2% to 15% of sunflower oil, 0.5% to 10% of shea butter, 1% to 4% of soybean sterol, and 1% to 50% of urea is explicitly specified in the original disclosure.

Additionally, claims 14 and 17 of the originally filed application recited dermatological compositions with ingredients in the concentration ranges specified in Table 1. These ingredients and concentration ranges are also specified in paragraphs [0011], [0013], [0015], [0016], [0027], [0033] and [0037] of the original application.

Accordingly, the limitations of “from 2% to 15% of sunflower oil,” “0.5% to 10% of shea butter,” “from 1% to 4% of soybean sterol,” “wherein the amount of sunflower oil in the composition is from 2% to 15%,” and “wherein the amount of shea butter in the composition is from 0.5% to 10% by weight,” that are recited in claims 49, 53, 56, 57, and 62, find explicit basis in the original disclosure of the present application.

The previously recited limitation, “wherein urea and water in combination constitute a major portion of the composition,” has been amended in claims 49 and 58, so that these claims recite “wherein urea and water in combination constitute at least 50% of the composition.” See the prior discussion herein, concerning the basis of support in the application for such limitation.

The limitations of “from 20% to 50% of urea,” “urea in the composition is from about 20 to about 41%,” and “wherein the amount of urea in the composition is from 20% to 50%,” in claims 49, 50, 55, and 59, have been cited in the rejection of such claims as lacking implicit or explicit support in the original disclosure.

Paragraph [0011] of the application discloses that “the invention relates to dermatological compositions including from about 1 to about 50 percent by weight of urea...” and that “in specific embodiments such compositions may have a urea concentration of from about 5 to about 40 percent by weight, or alternatively a concentration of from about 20 to about 40 percent by weight...” (Present application, pg. 3, ll. 17-22) Additionally, paragraph [0033] discloses that “[a]mounts of urea typically do not exceed above 50 weight percent, in order to provide optimal dermatological compatibility”(present application, pg. 9, ll. 1-3), and specifically discloses ranges of urea (about 5 to about 41%, about 10 to about 40%, and about 20 to about 40%) providing basis for recited ranges of the applicant’s claims.

Applicant respectfully directs the examiner’s attention in this respect to the following Section 2163.05 of the M.P.E.P., discussing amendments to the scope of a claim in regard to range limitations.

In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of “25%- 60%” and specific examples of “36%” and “50%.” A corresponding new claim limitation to “at least 35%” did not meet the description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, however, a limitation to “between 35% and 60%” did meet the description requirement. (emphasis added) (MPEP 2163.05 discussing *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976))

The limitations “from 20% to 50% of urea,” and “from about 20% to about 41%,” therefore find appropriate basis in the specification of the application. Under the standards of *In re Werthem* and MPEP § 2163.05, the limitations “from 20% to 50% of urea,” “urea in the composition is from about 20 to about 41%,” and “wherein the amount of urea in the composition is from 20% to 50%,” as recited by claims 49, 50, 55, and 59, are fully consistent with the written description requirement, and are supported by the disclosure in paragraph [0033] that “[i]n particular

embodiments, the amount of urea may be preferably in a range of from about 5 to about 41 percent, more preferably from about 10 to about 40 percent, and most preferably in a range from about 20 to about 40 percent” (present application, pg. 9, ll. 1-6).

Claims 52 and 61 have been rejected for purportedly failing to meet the written description requirement on the basis that the limitation “wherein the amount of sunflower oil in the composition is greater than the amount of shea butter,” is not explicitly stated in the original disclosure of the application. This rejection is traversed.

As stated above, the standard for determining compliance with the written description requirement in regard to a claim amendment is whether the disclosure reasonably conveys to one of skill in the art that the inventor had possession of the later claimed subject matter at the time of filing. (MPEP 2163.02)

Paragraph [0034] of the application discloses that the amounts of Shea butter and hybrid sunflower oil are advantageously utilized in the specified amounts to provide the desired level of emolliency in the composition. (Present application, pg. 9, ll. 7-12) The stated concentration range for shea butter, with an upper endpoint of 10%, is to be compared with the upper limit of 15% in the concentration range for sunflower oil. (Present application, Table 1) In addition, both the cream and the lotion formulations disclosed in paragraph [0055] and paragraph [0059] of the application contain concentrations of sunflower oil that are greater than the concentration of shea butter in the composition. (Present application, pg. 14, ln. 29 to pg. 16, ln. 5) Accordingly, the disclosure as filed reasonably conveys to one of skill in the cosmetic and pharmaceutical art that the applicant had possession at the time of filing of a dermatological composition in which the amount of sunflower oil in the composition is greater than the amount of shea butter.

For all these reasons, the limitations recited in claims 49-62 find support in the originally filed disclosure. Claims 49-62 therefore comply with the written description requirement under 35 USC § 112. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 103

In the May 1, 2008 Office Action the examiner rejected claims 49-62 under 35 U.S.C. 103(a) as being unpatentable over Huard et al. (US 6,485,733 B1; hereinafter 'Huard') in view of Quan et al. (US 6,180,133 B1; hereinafter 'Quan') in view of Durr et al. (US 5,997,889; hereinafter 'Durr') in view of Hill et al. (US 4,233,295; hereinafter 'Hill') and in view of McNulty et al. (US Publication 2005/0048105 A1; hereinafter 'McNulty') in view of Nagal et al. (1977; hereinafter 'Nagal').

The examiner repeated this rejection from the previous October 17, 2007 Office Action, contending that since each of the claimed constituents was already known in the prior art as being additives in lotions "either for moisturizing purposes or for antioxidant purposes to preserve the lotions/creams," the claims remain obvious in light of the prior art teachings. (Office Action, pg. 12, ll. 4-5) The examiner also rejected claim 54, which recites a composition "consisting of water; urea; disodium EDTA; sodium polyacrylate; stearic acid; glyceryl stearate; soybean sterol; shea butter; sunflower oil; butylated hydroxytoluene; and triethanolamine," as obvious in light of the prior references, despite the examiner's own acknowledgement that the prior art did not specifically describe a composition that "consists of" all of the ingredients of the composition recited by claim 54. (Office Action, pg. 12, ll. 9-18, claim 54) Applicant therefore traverses such rejections, for the following reasons.

Law Regarding Obviousness Rejections

To support a rejection under 35 U.S.C. 103, **the prior art reference(s) must teach all of the limitations of the claims.** (emphasis added) MPEP § 2143.03.

Additionally, when considering a reference for its effect on patentability, the reference is required to be considered in its entirety, including portions that teach away from the invention under consideration. Simply stated, the prior art must be considered as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (emphasis added); MPEP § 2141.02. "It is impermissible within the

framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 796 F.2d 443, 448 (Fed. Cir. 1986), cert. denied, 484 U.S. 823 (1987).

Limitations recited by claims 49 and 54, compositions/teaching of Huard and Durr

Claim 49, as amended, recites a dermatological composition, comprising water, from 20% to 50% urea, from 2% to 15% sunflower oil, and from 0.5% to 10% shea butter, wherein percentages of the urea, sunflower oil and shea butter are by weight based on total weight of the composition, and wherein urea and water in combination constitute greater than 50% by weight of the composition. (Claim 49)

The cited combination of references fails to teach all of the limitations of claim 49.

Huard describes an absorbent article composition for sequestering skin irritants that is a combination of Vaseline® Intensive Care Extra Strength Lotion and laponite clay. The Office Action cites the following passage from Huard for disclosing the ingredients of Vaseline™ Intensive Care Extra Strength Lotion.

“Ingredients present in Vaseline® Intensive Care Extra Strength Lotion include **(in order of decreasing concentration)**: water, glycerin, stearic acid, C11-13 isoparaffin, glycol stearate, triethanolamine, petrolatum, sunflower seed oil, glyceryl state, soya sterol, lecithin, tocopheryl acetate, retinyl palmitate, urea, collagen amino acids, sodium PCA, zinc oxide, cetyl phosphate, magnesium aluminum silicate, fragrance, steramide AMP, corn oil, methylparaben, DMDM hydantoin, iodopropynyl butylcarbamate and disodium EDTA.” (Huard, col. 18, ll. 51-63) (emphasis added)

As apparent from the above list of ingredients, Huard teaches a composition with no less than fourteen ingredients at a greater concentration than urea. Huard also discloses a composition that contains numerous additional ingredients that are not found in the compositions recited in claims

49 and 54 of the present application. Huard fails to teach a composition that contains shea butter. In addition, Huard teaches a composition that contains sunflower seed oil at a greater concentration than urea, which was previously pointed out by the Applicant in the response to the October 17, 2007 Office Action. Accordingly, Huard does not disclose or teach all of the limitations recited by claim 49. Specifically, Huard fails to disclose a composition that includes “from 20% to 50% urea, from 2% to 15% sunflower oil, and from 0.5% to 10% shea butter,” in which the percentages of the urea, sunflower oil and shea butter are by weight, based on total weight of the composition. Huard also fails to disclose a composition “wherein urea and water in combination constitute greater than 50% by weight of the composition.” (Claim 49)

In the May 1, 2008 Office Action, the examiner again cites Durr for disclosing that shea butter may be added to a lotion to improve its moisturizing ability, but discounts the Applicant's arguments pertaining to the lack of motivation of one of skill in the art to combine Huard and Durr due to the disparity between the ingredients of the compositions disclosed in Huard and Durr. (Office Action, pg. 11, ll. 8-9)

Additionally, Durr fails to teach or disclose a composition that includes “from 20% to 50% urea, from 2% to 15% sunflower oil, and from 0.5% to 10% shea butter,” in which the percentages of the urea, sunflower oil and shea butter are by weight based on total weight of the composition, and “wherein urea and water in combination constitute greater than 50% by weight of the composition.” (Claim 49)

The combination of Huard and Durr does not teach all of the limitations recited by claim 49, as required to support a rejection under 35 U.S.C. § 103. Since the additional cited references were cited for teaching ingredients not recited in claim 49, the composition recited by claim 49 is patentably differentiated over Huard in view of Durr. Applicant therefore respectfully requests that the rejection of claims 49 and claims 50-53, which depend from claim 49, be withdrawn.

In the May 1, 2008 Office Action the examiner also rejected claim 54, which recites a composition “consisting of water; urea; disodium EDTA; sodium polyacrylate; stearic acid; glyceryl stearate; soybean sterol; shea butter; sunflower oil; butylated hydroxytoluene; and triethanolamine,” as obvious in light of the prior references, despite the use of the transitional

phrase “consisting of,” and the examiner’s own acknowledgement that the prior art did not specifically describe a composition that “consists of” all of the ingredients of the composition recited in claim 54. (Office Action, pg. 12, ll. 9-18, claim 54)

The examiner’s attention is respectfully directed to section 2111.03 of the M.P.E.P. as set below. It is well settled law that

“[t]he transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (‘consisting of’ defined as ‘closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.’)” MPEP 2111.03

Accordingly, the subject matter of claim 54, and claims 55-62 which depend therefrom, is not disclosed in or derivable from the cited combination of Durr and Huard, which fail to include all of the ingredients of the composition recited by claim 54. As such, Applicant respectfully requests that this rejection be withdrawn.

Obviousness under *KSR International Co. v. Teleflex Inc.*, lack of motivation to combine Huard and Durr

In the May 1, 2008 Office Action, the examiner frequently cites *KSR International Co. v. Teleflex Inc.*, 127 S.Ct 1727, 167 L.Ed.2d 705, 82 USPQ2d 1385 (April 30, 2007) for the propositions that “KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness,” and that “...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” (Office Action, pg. 10, paragraph 1, and pg. 12, paragraph 2)

Applicant respectfully directs the examiner’s attention to the fact that in *KSR International Co. v. Teleflex Inc.*, the court did not disavow the previous “teaching, motivation or suggestion” or “TSM” test, but stated that such TSM text *should not be strictly applied* in determining obviousness. In connection with this point, the Supreme Court stated that:

“A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. ... [Rather], it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant art to combine the

[prior art] elements in the manner claimed.” (emphasis added) *KSR*, 82 USPQ2d at 1389.

It is fundamental to a proper rejection of claims under 35 U.S.C. § 103 that an examiner must present a **convincing line of reasoning supporting the rejection**. MPEP 2144 (“Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103”), citing *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). The Supreme Court in *KSR* stated that **“there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”** (emphasis added) *KSR*, 82 USPQ2d at 1396.

In the May 1, 2008 Office Action, the examiner acknowledges that the cited references “do not specifically teach the amounts of constituents as instantly claimed...” but reiterates the rationale for the rejection that “each of the claimed constituents was already know in the prior art as being additives in lotions.” The examiner contends that since “[t]he ordinary artisan was fully aware that each of the claimed ingredients was well known to be used in the cosmetic feild [sic] in lotions,” that any composition with these ingredients, no matter the claimed concentrations is obvious. (Office Action, pg. 11, ll. 5-7 and pg. 12, ll. 4-10) As stated by the Supreme Court in *KSR*, “[a] patent composed of several elements is not proved obvious **merely by demonstrating that each element was, independently, known in the prior art.**” (emphasis added) *KSR*, 82 USPQ2d at 1389.

The Supreme Court further confirmed in *KSR* that **references that teach away from the invention are evidence of the non-obviousness** of a claimed invention. (emphasis added) (*KSR*, 82 USPQ2d at 1395, 1399).

Huard clearly teaches that there is a synergistic benefit obtained from the combination of the ingredients present in the Vaseline® Intensive Care Extra Strength Lotion and the laponite clay suspension. “Surprisingly, the combination of VISL [Vaseline® Intensive Care Extra Strength Lotion] with the laponite caused a synergistic increase in the reduction of the trypsin through the skin model.” (Huard, col. 19, ll. 60-63) Durr clearly teaches an entirely different composition than Huard, describing a hand and body crème that comprises very little water, in contrast to Huard, and at least 70% by volume of “cocoa butter, almond oil, jojoba oil, vitamin E oil, a

commercially available beeswax derivative, hydrogenated soybean flakes, pure beeswax, and vitamin A oil.” (Durr, Abstract, and col. 5, ll. 61-66)

Accordingly, there is no motivation for one of skill in the art to combine the teaching of Durr with Huard. One of skill in the pharmaceutical and cosmetic art would not be motivated to combine Durr and Huard, not only due to the disparity between the stated ingredients of the compositions, but also for fear of disrupting the synergistic effect that is obtained from the specific combination of the ingredients disclosed in the Vaseline® Intensive Care Extra Strength Lotion formulation. Huard teaches that this synergy is only demonstrated by the combination of laponite and the Vaseline® Intensive Care Extra Strength Lotion formulation, and not by laponite alone or by the Vaseline® Intensive Care Extra Strength Lotion alone. (Huard, col. 19, ll.60-63, Fig. 7) As such, the teaching of Huard does not provide one of skill in the art with sufficient motivation to combine the ingredients disclosed in the composition in Huard with the ingredients of the composition disclosed in Durr. Accordingly, the compositions recited in independent claims 49 and 54 are non-obvious over Huard in view of Durr, and the Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

Based on the foregoing, all of Applicants’ pending claims 49-62 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

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